



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0436; FRL-8806-01-OCSPP]

Di-isononyl Phthalate (DINP); Final Scope of the Risk Evaluation to be Conducted under the Toxic Substances Control Act (TSCA); Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Toxic Substances Control Act (TSCA) and implementing regulations, EPA is announcing the availability of the final scope of the risk evaluation to be conducted for di-isononyl phthalate (DINP) (1,2-benzene-dicarboxylic acid, 1,2-diisononyl ester, and 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich; Chemical Abstracts Service Registry Number (CASRN) 28553-12-0 and CASRN 68515-48-0), a category of chemical substances for which EPA received a manufacturer request for risk evaluation. The scope document includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations that EPA plans to consider in conducting the risk evaluation for this category of chemical substances.

ADDRESSES: The docket, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0436, is available online at <http://www.regulations.gov> or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Collin

Beachum, Existing Chemical Risk Assessment Division (Mailcode E205-02), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 109 T.W. Alexander Drive, RTP, NC 27711; telephone number: (919) 541-7554; email address: *beachum.collin@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to entities that manufacture (including import) a chemical substance regulated under TSCA (*e.g.*, entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). The action may also be of interest to chemical processors, distributors in commerce, and users; non-governmental organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What is the Agency's authority for taking this action?

The final scope document is issued pursuant to TSCA section 6(b)(4)(D) and EPA's implementing regulations at 40 CFR 702.41(c)(8).

C. What action is the Agency taking?

EPA is publishing the final scope of the risk evaluation for DINP under TSCA. Through the risk evaluation process, EPA will determine whether the category of chemical substances presents an unreasonable risk of injury to health or the environment under the conditions of use, as determined by the Administrator, in accordance with TSCA section 6(b)(4).

II. Background

TSCA allows chemical manufacturers to request an EPA-conducted risk evaluation of a chemical substance under 40 CFR 702.37. On May 24, 2019, EPA received a manufacturer request for a risk evaluation of DINP (Ref. 1). On December 2, 2019, the Agency granted the request and subsequently initiated the scoping process for a risk evaluation for this category of chemical substances on January 2, 2020. Pursuant to 40 CFR 702.41(c)(7), EPA announced the availability of and sought public comment on the draft scope document for the risk evaluation to be conducted for DINP under TSCA (85 FR 76072, November 27, 2020) (FRL-10017-15) (Ref. 2).

The purpose of risk evaluation is to determine whether a chemical substance, or group of chemical substances, presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation (15 U.S.C. 2605(b)(4)(A)). As part of this process, EPA must evaluate both hazards and exposures for the conditions of use; describe whether aggregate or sentinel exposures were considered and the basis for consideration; not consider costs or other nonrisk factors; take into account where relevant, likely duration, intensity, frequency, and number of exposures and describe the weight of the scientific evidence for hazards and exposures (15 U.S.C. 2605(b)(4)(F)). This process will culminate in a determination of whether or not the category of chemical substances presents an unreasonable risk of injury to health or the environment under the conditions of use (15 U.S.C. 2605(b)(4)(A); 40 CFR 702.47).

III. Information and Comments Received on the Draft Scope

In the Federal Register of November 27, 2020 (Ref. 2), EPA announced the availability of the draft scope document for the risk evaluation to be conducted for DINP under TSCA and invited public comments on EPA's draft scope document, including additional data or information relevant to the category of chemical substances or that otherwise could be useful to the Agency in finalizing the scope of the risk evaluation. To the extent that comments provided information on conditions of use, as well as other elements of the draft scope document. Those

comments and other submitted information (*e.g.*, relevant studies and assessments) were used to inform revisions to the draft scope document and may be considered in subsequent phases of the risk evaluation process.

EPA received six unique submissions for DINP, including comments from potentially affected businesses or trade associations, environmental and public health advocacy groups (some submissions were signed by more than one group), a group of state attorneys general, and one anonymous comment.

Comments addressed the overall approach to the risk evaluation process (*e.g.*, collection, consideration, and systematic review of relevant information), the specific elements of the scope document (*e.g.*, hazard, exposure, and potentially exposed or susceptible subpopulations), information specific to the chemical substances (*e.g.*, relevant studies, assessments, and conditions of use), and topics beyond the draft scope document phase of the process (*e.g.*, risk management). EPA considered those comments, as applicable and appropriate, in developing the final scope document. Concurrently with the publication of the final scope document, EPA is publishing a response to comments document that contains a comprehensive summary of and response to public comments received on the DINP draft scope document. The comprehensive response to comments document is available in the docket EPA-HQ-OPPT-2019-0436 (Ref. 3).

IV. References

The following is a listing of the documents that are specifically referenced in this *Federal Register* notice. The docket for this action includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket. For assistance in locating these referenced documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Di-isononyl Phthalate (DINP) (1,2-Benzene- dicarboxylic acid, 1,2-diisononyl ester); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments. *Federal Register*. (84 FR 42912,

August 19, 2019) (FRL-9998-25).

2. EPA. Di-isononyl phthalate (DINP); Draft Scope of the Risk Evaluation To Be Conducted Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments. Federal Register. (85 FR 76072, November 27, 2020) (FRL-10017-15).

3. EPA. EPA Response to Public Comments Received on the Draft Scopes of the Risk Evaluations Under the Toxic Substances Control Act (TSCA) for: Di-isodecyl Phthalate (DIDP) (1,2-Benzenedicarboxylic acid, 1,2-diisodecyl ester and 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich) CASRN 26761-40-0 and 68515-49-1 and Di-isononyl Phthalate (DINP) (1,2-Benzene-dicarboxylic acid, 1,2-diisononyl ester, and 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich) CASRNs 28553-12-0 and 68515-48-0. (August 2021).

Authority: 15 U.S.C. 2601 *et seq.*

Michael S. Regan,

Administrator.

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